

REMARKS

Status of the Claims

Claims 1-30 are pending in this application. Claims 11-13, 17, 19 and 24-30 are amended herein. Support for the amendments to the claims can be found in the specification, figures and claims as originally filed. Applicants submit that the amendments to the claims introduce no new matter.

Applicants respectfully thank the Examiner for indicating that claims 9-14 and 25-30 are allowed and that claim 24 would be allowable if rewritten in independent form including all the limitations of the base claim and any intervening claims. Accordingly, Applicants amend claim 24 into independent form including limitations of its base claim and other intervening claims. Furthermore, claims 11-13, 17, 19 and 25-30 have been amended in order to be brought into conformity with the wording of claims 1, 16 and 17.

Rejection Under 35 U.S.C. § 102

Claims 16-23 were rejected under 35 U.S.C. § 102(b) as being anticipated by International Publication No. WO 99/62580 to Sinderby *et al.* (“Sinderby”). Applicants respectfully traverse the rejection for at least the reasons set forth below.

The Office action alleges that Sinderby, even though it may not disclose sensing electrical activity during expiration, is certainly capable of sensing such activity and controlling the level of pressure as claimed (in Applicants’ claims 16-23), especially since all of the required components to achieve such function are disclosed by Sinderby.

More specifically, the Office action alleges that Sinderby discloses an apparatus for controlling positive pressure assist to a patient during expiration comprising a detector of a level of electrical activity of a patient’s respiration-related muscle and a controller that includes a neuro-ventilatory efficiency computation device 601 to control the operation of a level of pressure assist by unit 604. Furthermore, the Office action alleges that Sinderby also discloses a control arrangement 700 in Figure 11 to detect levels of EMG intensity to control the automatic operation of PEEP ventilation.

Applicants respectfully submit that Sinderby does not teach or suggest the limitation introduced in claims 16 and 17 that the controller (or the means for adjusting the level of positive pressure assist) also minimizes the level of electrical activity of the patient's respiration-related muscle during expiration. Such electrical activity level minimizing controls the stress on the respiration-related muscle while avoiding patient's lung collapse.

As already mentioned by the Examiner, Sinderby discloses a system for adjusting a level of inspiratory support in proportion to changes in the neuro-ventilatory efficiency so that the neural drive remains stable. Sinderby's neuro-ventilatory efficiency is a function of the electromyographic (EMG) signal and a given inspiratory volume (*see*, Sinderby at abstract).

More specifically, Sinderby's control arrangement 700 in Figure 11 controls the level of applied extrinsic PEEP. For that purpose, Sinderby's control arrangement comprises a neuro-ventilatory delay calculator 704, responsive to the detection of the onset of inspiratory flow given by an inspiratory flow detector 702. If the detected level of Sinderby's EMG intensity at the onset of inspiratory flow is higher than a given limit, then the level of applied extrinsic PEEP is either automatically or manually increased (device 708). If the detected level of Sinderby's EMG intensity at the onset of inspiratory flow is lower than a given limit, then the level of applied extrinsic PEEP is either automatically or manually decreased (device 711) – (see from page 21, line 20 to page 23, line 23).

Therefore, Applicants respectfully submit that, with this control arrangement, Sinderby fails to teach or suggest control of the stress on a respiration-related muscle while avoiding patient's lung collapse. Sinderby also fails to teach or suggest the use, to reach this result, of the means or controller for minimizing the level of electrical activity of the patient's respiration-related muscle during expiration with the result that stress on the respiration-related muscle is controlled while patient's lung collapse is avoided.

Applicants' present invention is not restricted to sense electrical activity of the patient's respiration-related muscle during expiration and controlling a level of pressure assist to the patient during expiration, but also using the above features to minimize the level of electrical activity of the patient's respiration-related muscle during expiration which leads to control of the stress of the respiration-related muscle while avoiding patient's lung collapse.

Accordingly, at least for the above reasons, Applicants respectfully submit that claims 16 and 17 contain subject matter which distinguishes the present invention over the teaching of Sinderby. Dependent claims 18-23, which are directly or indirectly dependent upon claim 17, are believed to also contain subject matter which distinguishes the present invention over the teaching of Sinderby for at least the same reasons as claim 17. Applicants respectfully request that the rejection of claims 16-30 under 35 U.S.C. § 102 be reconsidered and withdrawn.

Rejection Under 35 U.S.C. § 103

Claims 1-8 and 15 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Sinderby. Applicants respectfully traverse the rejection for at least the reasons set forth below.

In this regard, the Office action alleges that Sinderby's device includes all the required components to practice the method as claimed, since this device is certainly capable of measuring a level of electrical activity of a patient's diaphragm during expiration and controlling a level of pressure assist during such expiration event and practicing the method as claimed.

Claim 1 is the method counterpart of the device claim 16, discussed above with respect to Sinderby. Therefore, claim 1 recites substantially the same features as claim 16. Therefore, the remarks presented above with respect to the rejection of claims 16-23 under 35 U.S.C. § 102(b) in view of Sinderby equally apply to claim 1. According, Applicants respectfully submit that claim 1 contains subject matter which distinguishes the present invention over the teaching of Sinderby.

Since claims 2-8 and 15 depend directly or indirectly upon independent claim 1, which is believed to distinguish the present invention from the cited reference, it is believed that these claims also contain subject matter which distinguishes the present invention over the teaching of Sinderby. Applicants respectfully request that the rejection of claims 1-8 and 15 under 35 U.S.C. § 103 be reconsidered and withdrawn.

Summary

In view of the above arguments, Applicants respectfully submit that claims 1-30 are allowable over the teaching of Sinderby. Accordingly, Applicants submit that claims are in condition for allowance.

Respectfully submitted,

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